4.*Implementation guidelines:* These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual, ''Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf: 45–13, and the Department's Automated Information System Security Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the FDA Records Control Schedule transmittal number H:90–1, Departmental number B–331.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Inspections and Surveillance (HFM–650), Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, 1401 Rockville Pike, Rockville, MD 20852.

Director, Division of Bioresearch Monitoring (HFZ–310), Office of Compliance, Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

Deputy Director, Division of Scientific Investigation (HFD–341), Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Pl., Rockville, MD 20855.

Bioresearch Monitoring Project Manager (HFS–207), Center for Food Safety and Applied Nutrition, Office of Premarket Approval, Division of Product Policy, 200 C St. SW., Washington, DC 20204.

Manager, Bioresearch Monitoring Program (HFV–234), Center for Veterinary Medicine, Division of Compliance, 7500 Standish Pl., Rockville, MD 20855.

NOTIFICATION PROCEDURES:

An individual may learn if a record exists about him or her upon written request with notarized signature or certification of identification under penalty of perjury if request is made by mail, or with identification if request is made in person (see also 21 CFR 21.44), directed to:

FDA Privacy Act Coordinator (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the system manager. If access is denied to requested records, an appeal may be made to:

Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

You may also request an accounting of disclosures that have been made of your record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Individual on whom the record is maintained. Some material is obtained from third parties, e.g., drug companies, publications, or is developed by FDA.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system is exempt from access and contest and certain other provisions of the Privacy Act (5 U.S.C. 552a(c)(3), (d)(1) to (d)(4), (e)(3), (e)(4)(G) to (e)(4)(H) and (f)) to the extent that it includes investigatory material compiled for law enforcement purposes, where access would be likely to prejudice the conduct of the investigation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0135]

Agency Information Collection Activities; Announcement of OMB Approval; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''OTC Test Sample Collection Systems for Drugs of Abuse Testing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 5, 1998 (63 FR 10792), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0368. The approval expires on April 30, 2001.

Dated: October 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 23, 1998, the comment period for the draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of July 24, 1998 (63 FR 39880). FDA is taking this action in response to several requests for an extension.

DATES: Written comments on the draft guidance may be submitted by November 23, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft